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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,111	09/15/2000	Charles J. Davidson	19601-000320US	3759

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	09/663,111		DAVIDSON ET AL.	
	Examiner		Art Unit	
	Paul B. Prebilic		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-19, 42-48 and 50-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-19, 42-48, 50, 51 and 53-70 is/are rejected.
- 7) ☒ Claim(s) 8 and 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/1/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3738

Claim Objections

Claim 2 is objected to because of the following informalities:

Regarding claim 2, the language of this claim repeats language found in base claim 1. For this reason, it does not clearly further modify claim 1 and is improper in view of 37 CFR 1.75(b). Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 51, 53, 59, 60, 63, and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8, 9, 12, 15, and 21 of U.S. Patent No. 6,692,483. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are broader in scope but are readable on the present claims. For this reason, the present claims are considered to be clearly obvious over the patented claims of 6,692,483. In other words, if the present claims were considered to be prior art, they could be used to "anticipate" the patented claims.

Art Unit: 3738

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 10, 11, 13, 18, 42-48, 50, 51, 53, 56, 59, 60, 63, 65-68, and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al (US 6,165,195). Wilson anticipates the claim language where the side member is lumen 55A that has an unattached end that springs away from catheter (35) to redirect the guidewire; see Figures 12J to 12L, column 15 where this figure is described and the paragraph bridging columns 17 and 18. Since all the elements of the Wilson device can be made radiopaque, the claim language requiring radiopaque markers in the catheter and side member is fully met.

Regarding claim 5, since both the stent and the catheter can be radiopaque, the claim language is fully met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3738

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 10, 11, 12, 15, 18, 42, 45, 48, 50, 51, 53-55, 58-60, 63, 65, and 66 are rejected under 35 U.S.C. 102(e) as anticipated Duffy et al (US 6,086,611) by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Duffy et al (US 6,086,611) in view of Wilson et al (US 6,165,195). Duffy anticipates the claim language where the catheter is the upper balloon catheter (4) of Duffy (see Figure 6B), and the side member as claimed is the lower balloon catheter. The guidewire lumens of Duffy are inherently present since they are shown holding guidewires (19). The radiopaque markers as claimed are connectors (9); see the abstract, Figures 1 to 4 (especially Figure 2 that shows markers that can be adjacent when in the straight configuration of Figure 4), and column 5, lines 48-63. The movement of the side branch as claimed is at the deployment site; see column 6, lines 6-54 and Figures 6A to 7F. The side hole as claimed is any hole between wires of the modules (11). The catheter and side member of Duffy are at least fixedly attached to each other by the stent of Duffy that holds the balloons thereof together.

Alternatively, one may not consider the catheter and side member of Duffy as being fixedly attached to each other because there is no clear direct attachment of the two disclosed. However, with this interpretation, Wilson teaches that it was known to attach two adjacent balloons to each other when a similar type stent is inserted into a bifurcation; see Figures 27A, 28, 30, and 31. Therefore, it is the Examiner's position that it would have been at least obvious to attach the catheter and side member of Duffy to each other (i.e. adjacent balloons) for the same reasons that Wilson does the same

Art Unit: 3738

or in order to prevent slipping of the adjacent balloons from an aligned position during deployment.

Regarding claim 10, the side hole as claimed is at the "crotch" of the stent of Duffy.

Claims 16, 17, 19, 61, 62, 64, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy et al (US 6,086,611) alone.

Regarding claims 16, 17, 61, and 62, Duffy fails to disclose a balloon inflation lumen, channels, and ports. However, since Duffy discloses balloons that can be inflated by an operator of the device, it would have been obvious to have a lumen with channels and ports to deliver the inflation fluid to the balloons. In other words, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have such features in Duffy because Applicants have not disclosed that having such provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because the a functional set of balloons is all that is necessary. Therefore, it would have been an obvious matter of design choice to modify Duffy to obtain the invention as specified in the claims.

Regarding claims 19 and 64, Duffy fails to disclose the length of the detachment of the elements designated as the catheter and side member. However, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a 2 to 10 cm detachment length because Applicants have not disclosed that having such provides some advantage, is used for a particular purpose, or solves a stated problem.

Art Unit: 3738

One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because it would be suitably sized for the particular bifurcation point. Therefore, it would have been an obvious matter of design choice to modify Duffy to obtain the invention as specified in the claims.

Regarding claim 69, Duffy fails to disclose a connector as claimed. However, since the stent performs the same function as a connector and since one could designate one module as the connector, the claimed invention would have been at least prima facie obvious to an ordinary artisan.

Claims 14 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy et al and Wilson et al as applied to claims 1-7, 10, 11, 12, 15, 18, 42, 45, 48, 50, 51, 53-55, 58-60, 63, 65, and 66 above, and further in view of Davila et al (US 5,851,464). Duffy fails to disclose the use of pebax and graphite in the catheters. However, Davila teaches that it was known to make catheters out of pebax and graphite; see column 3, lines 8-32. Therefore, it is the Examiner's position that it would have been prima facie obvious to make the catheter of Davila out of pebax and graphite for the same reasons that Davila did the same and in order to promote sliding between the catheter and guidewire.

Allowable Subject Matter

Claims 8 and 52 are objected to as containing allowable subject matter but dependent upon a rejected base claim. However, if these claims were rewritten in independent form included all the limitations of the base claim and any intervening claim, they would be allowable.

Art Unit: 3738

Conclusion

Applicants' submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on June 1, 2004 prompted the new ground(s) of rejection presented in this Office action. However, since the Wilson et al patent and the Vardi et al patent, as applied above, were already of record from an earlier information disclosure statement, the Examiner has made this action non-Final.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action unless such applications are stored in image format (i.e. IFW). Generally, those applications filed or amended after July 1, 2003 are image file wrapper (IFW) applications.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Prebilic whose telephone number is (571) 272-4758. The examiner can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738